



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,551	10/17/2003	Indranil Nandi	G-33422P1/GPI	1169
1095	7590	10/11/2006	EXAMINER	
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			AZPURU, CARLOS A	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/688,551	Applicant(s) NANDI ET AL.	
	Examiner Carlos A. Azpuru	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 14-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the request for continued examination filed 08/31/2006.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Itoh et al (US Patent No 6,221,402).

Itoh et al disclose a taste-masking composition comprising a (1) core, (2) inner coating layer, and (3) outer coating layer (see Abstract). The core particles disclosed by Itoh et al have an average particle diameter between 80 and 400 microns (column 3, lines 37-45). According to Itoh et al, antibiotics such as erythromycin may be used as an active agent composition (col. 2, line 61 – col. 3, line 12) and may be present in a range between 20-40% by weight (col. 3, line 46-58). The inner coating and core may comprise hydroxymethylpropyl cellulose (tables 1(a), 1(b), 1(c) and col. 6, lines 36-37). The outer cores may comprise Eudragit E100 (col. 7, lines 1-11 and Tables 1(a), 1(b), and 1(c)). The method of administration is considered an intended use of a known

composition. Further, while applicant's claims read on an "inner coating consisting essentially of at least one cellulose polymer which is not an enteric coating polymer, hydroxymethylpropyl cellulose meets that limitation of "at least one which is not an enteric coating polymer". The existence of enteric coating polymers such as EUDRAGIT NE 30 D in this inner coating does not change the fact that "at least one" cellulose polymer is not an enteric coating polymer. As such, this limitation is fully met. The instant claims are clearly anticipated by Ito et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Itoh et al as applied to claims 1-7, 9-13 above, and further in view of Ullah et al (US Patent No. 6,331,316).

Itoh et al disclose a taste-masking composition comprising a (1) core, (2) inner coating layer, and (3) outer coating layer (see Abstract). The core particles disclosed by Itoh et al have an average particle diameter between 80 and 400 microns (column 3, lines 37-45). According to Itoh et al, antibiotics such as erythromycin may be used as an active

agent composition (col. 2, line 61 – col. 3, line 12) and may be present in a range between 20-40% by weight (col. 3, line 46-58). The inner coating and core may comprise hydroxymethylpropyl cellulose (tables 1(a), 1(b), 1(c) and col. 6, lines 36-37). The outer cores may comprise Eudragit E100 (col. 7, lines 1-11 and Tables 1(a), 1(b), and 1(c)). The method of administration is considered an intended use of a known composition. Further, while applicant 's claims read on an "inner coating consisting essentially of at least one cellulose polymer which is not an enteric coating polymer, hydroxymethylpropyl cellulose meets that limitation of "at least one which is not an enteric coating polymer". The existence of enteric coating polymers such as EUDRAGIT NE 30 D in this inner coating does not change the fact that "at least one" cellulose polymer is not an enteric coating polymer. As such, this limitation is fully met. The ordinary practitioner would have found it well within their skill to claim an enterically coated composition comprising a core, inner coating wherein at least one cellulose polymer is not an enteric coating polymer, and an outer enteric coating given the teachings of Itoh et al. Itoh et al however, does not specifically recite the use of poly(methacrylic acid, ethyl acrylate) 1:1 as an enteric coating.

Ullah et al disclose an enteric coated pharmaceutical tablet comprising an antibiotic such as erythromycin (see Abstract and col. 5, line 40). Multiple coatings with a top enteric coating are found at col. 7, lines 5-19. Ullah et al further teaches the advantage of coating a tablet with polymethacrylic acid ethyl acrylate) because it remains stable while in the stomach, but disintegrates in the small intestine (col. 4, lines

53-67). Therefore, those of ordinary skill would have found it well within their skill to modify the outer enteric coating in a multiple layer composition as taught by Itoh et al, by specifically using poly(methacrylic acid ethyl acrylate) 1:1, for its known advantages and enteric drug delivery properties as taught by Ullah et al. The ordinary practitioner would have had a reasonable expectation of similar enteric drug delivery, and consequent therapeutic results by combining the teachings of Itoh et al, and specifically using the poly(methacrylic acid ethyl acrylate) coating as taught by Ullah et al. The instant invention would have therefore been obvious to one of ordinary skill in the art at the time of invention given the combined teachings of Itoh et al in view of Ullah et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

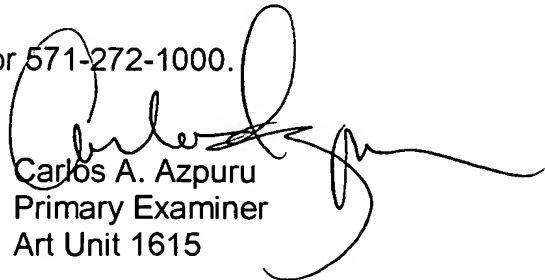
Claims 1-8, 12-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 6, 10-12, 16-17 of copending Application No. 10/768,562 (US'562). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'562 claims an antibiotic composition comprising (1) a core comprising an antibiotic, (2) an inner coating comprising a cellulose polymer which is not an enteric coating polymer, and (3) an outer coating comprising at least one enteric coating polymer (see claim 1). The particle size is between about 100 microns to about 650 microns (see claim 1). The cellulose polymer of the inner core is specifically recited as hydroxymethylpropyl cellulose at claim 6, and the enteric polymer coating is specifically recites as poly(methacrylic acid ethyl acrylate) at claim 12. Therefore, those of ordinary skill would have expected similar enteric drug delivery, as well as similar therapeutic results from the use of the instant composition given the claims of copending US'562. The instant claims would have therefore been obvious at the time of invention given the claims of copending US'562.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Carlos A. Azpuru
Primary Examiner
Art Unit 1615

ca